



Long Comment Regarding a Proposed

This is a Word document that allows users to type into the spaces below. The comment may be single-spaced, but should be in at least 12-point type. The italicized instructions on this template may be deleted.

Please submit a separate comment for each proposed class.

NOTE: This form must be used in all three rounds of comments by all commenters not submitting short-form comments directly through regulations.gov, whether the commenter is supporting, opposing, or merely providing pertinent information about a proposed exemption.

When commenting on a proposed expansion to an existing exemption, you should focus your comments only on those issues relevant to the proposed expansion.

[] Check here if multimedia evidence is being provided in connection with this comment

Commenters can provide relevant multimedia evidence to support their arguments. Please note that such evidence must be separately submitted in conformity with the Office's instructions for submitting multimedia evidence, available on the Copyright Office website at <https://www.copyright.gov/1201/2018>.

ITEM A. COMMENTER INFORMATION

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ITEM B. PROPOSED CLASS ADDRESSED

Proposed Class 12: Computer Programs - 3D Printing

ITEM C. OVERVIEW

The Proposed Class proposes to eliminate qualifying language that exists within the current Class 26 - Software - 3D Printers. The qualifying language is problematic for at least two reasons. First, it establishes a vague and unworkable standard for applying the existing exemption that effectively eliminates its applicability in the vast majority of situations. Second, the qualifying language is grounded in concerns that are properly addressed by other regulatory agencies, to the extent that they must be addressed at all.

ITEM D. TECHNOLOGICAL PROTECTION MEASURE(S) AND METHOD(S) OF CIRCUMVENTION

The TPMs in question for the proposed exemption are identical to those involved in current (and recommended for renewal) Class 26. They are computer programs that operate 3D printers that employ TPMs to limit the

Privacy Act Advisory Statement: Required by the Privacy Act of 1974 (P.L. 93-579)

The authority for requesting this information is 17 U.S.C. §§ 1201(a)(1) and 705. Furnishing the requested information is voluntary. The principal use of the requested information is publication on the Copyright Office Web site and use by Copyright Office staff for purposes of the rulemaking proceeding conducted under 17 U.S.C. § 1201(a)(1). NOTE: No other advisory statement will be given in connection with this

use of feedstock, when circumvention is accomplished solely for the purpose of using alternative feedstocks and not for the purpose of accessing design software, design files or proprietary data.

ITEM E. ASSERTED ADVERSE EFFECTS ON NONINFRINGEMENT USES

As the Copyright Office has already recommended the renewal of current Class 26, this comment will not attempt to repeat the arguments and highlight adverse effects relevant to that exemption more broadly. Instead, this comment focuses on the harms created by the qualifying language in the current exemption targeted in this proposed class:

“that the exemption shall not extend to any computer program on a 3D printer that produces goods or materials for use in commerce the physical production of which is subject to legal or regulatory oversight or a related certification process, or where the circumvention is otherwise unlawful.”

As detailed below, this language is ambiguous enough to significantly reduce or eliminate the existing exemption. Individual 3D printers are often used for a mix of commercial and noncommercial purposes and most physical objects are subject to at least some level of legal oversight. As such, the qualifying language can be credibly read to excludes almost all 3D printers and therefore reinstates the harms that justified the exemption in the first place.

Furthermore, the qualifying language was included in the exemption in an attempt to address a harm related to industrial and medical safety that was not adequately established in the record. To the extent that these types of harms do exist, remedying them is well beyond the scope of copyright law and any remedies are best crafted by expert regulatory agencies.

With real costs and limited benefits, the qualifying language should be removed from the exemption.

Background

In order to understand the history and purpose of the qualifying language, it is helpful to trace its original justification and evolution through the previous rulemaking process.

Comments

The search for non-copyright-related impacts of the exemption appears to have been first raised by the 3D printing company Stratasys. In its opposition comments, Stratasys raised the possibility that “[u]se of non-genuine materials in 3D printers also may cause unexpected health issues.”¹

¹ See Comments of Stratasys, Ltd., *In the Matter of Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies*, Docket No:

Stratasys also pointed out that TPMs might have benefits to users unrelated to copyright: “chipped or ‘smart’ cartridges permit printers to measure the amount of material remaining in a cartridge and to notify the printer operator when replacement or service is required.”² Notably, neither of these concerns were related to the protection or availability for use of copyrighted works. Nor did they cite evidence to validate their existence. Nor did they explain why a user willing to forego these benefits should be prevented from doing so for a reason related to copyright law.

Roundtable

Stratasys expanded its discussion of non-copyright-related concerns during the roundtable discussions of the proposed exemption by noting that 3D printers are used in the aviation industry: “[s]o the highly integrated machine that produces, that takes the material that prints it in an FAA-certified part is extremely important, highly integrated machine, for parts to be on a commercial airplane.”³ Stratasys did not fully explain why the fact that some 3D printers are used in the aviation industry should prevent informed users from making use of third party feedstock in their own printers. It also did not explain why existing FAA regulations were inadequate to guarantee the safety and integrity of airline parts regardless of their method of manufacture.

The Copyright Office panel further explored this concern, making it clear that it was grounded in safety and counterfeit concerns outside of the scope of copyright law:

“Is part of the fear here is that someone that’s not in the normal stream, manufacturing stream, or one of these normal manufacturer that’s used to doing this, that goes and goes around the TPM, gets hold of inferior materials, and then tried to put that part into the manufacturing stream and somehow passes it off, is that what the fear is here, is that there is sort of not just a competition issue but that somebody outside of the normal chain inserts an inferior part and that somehow makes it through the process? . . . And so the fear is that one of these downstream manufacturers, second tier or whatever, that they would somehow break the TPM, install an inferior material into the part, and then it goes up the chain without being tested adequately or otherwise.”⁴

RM 2014-07, (Mar. 27, 2015), available at https://copyright.gov/1201/2015/comments-032715/class%202026/STRATASYS_Class26_1201_2014.pdf [“Stratasys Comments”] at 29.

2 *Id.* at 28

3 Transcript of *Library of Congress United States Copyright Office Triennial 1201 Rulemaking Hearing*, (May 28, 2015) availabe at <https://www.copyright.gov/1201/2015/hearing-transcripts/1201-Rulemaking-Public-Roundtable-05-28-2015.pdf> at 154.

4 *Id.* at 159-60.

It is noteworthy that the item being manufactured in this discussion is not a copyrighted work. Instead, it is a functional part that is manufactured by a machine that may use software to verify the provenance of its input material. While important, in the words of the Copyright Office representatives, the concern was “a concern about the integrity of the products that are being certified by I guess regulatory agencies.”⁵ No evidence was provided to suggest that TPMs have any impact on actors intending to introduce inferior products into the supply chain.

The Copyright Office should not be expected to understand the nuances of every type of regulatory regime in the United States. However, the fact that the agency in charge of ensuring material safety in aviation was so far removed from the Copyright Office’s core function as to be unknown (“...products that are being certified by I guess regulatory agencies”) suggests that this proceeding is not the proper venue for its consideration. It is unreasonable to expect the Copyright Office to understand every regulatory landscape in the United States, let alone develop a nuanced understanding of how TPMs might impact those existing rules.

Additional Questions

The Copyright Office submitted an additional written question to the participants after the roundtable.⁶ It highlighted concerns that “parts made with substantial materials could enter the commercial supply chain and pose risks to the public.” As noted above, the parts in question were not works protected by copyright. Instead, the Copyright Office’s questions appeared to be motivated by product safety concerns. In light of those concerns, the Copyright Office asked participants “whether an exemption could or should differentiate between ‘commercial’ versus other types of uses.”

Both proponents and opponents replied that such a distinction was neither possible nor desirable. Commenter provided examples where the distinction between consumer and professional users blurred.⁷ Commenter further noted that there were legitimate reasons why exclusively commercial users of 3D printing would want to make use of third party feedstocks.

5 *Id.* at 176.

6 Letter from Jacqueline C. Charlesworth, General Counsel and Associate Register of Copyrights, to Stratasys, Ltd. et al, *re: Docket No. 2017-7 Exemptions to Prohibition Against Circumvention of Technological Measures Protecting Copyrighted Works*, (June 3, 2015) available at <https://copyright.gov/1201/2015/post-hearing/Post%20hearing%20questions%20for%20class%2026-signed.pdf>.

7 See Letter from Michael Weinberg to Jacqueline C. Charlesworth, General Counsel and Associate Register of Copyrights, *re: Docket No. 2017-7 Exemptions to Prohibition Against Circumvention of Technological Measures Protecting Copyrighted Works*, (June 29, 2015) available at https://copyright.gov/1201/2015/post-hearing/answers/Class_26_Hearing_Response_Weinberg_Docket_No_2014-07_2015.pdf.

Stratasys also highlighted the challenges with attempting to differentiate between commercial and noncommercial users, titling the first section of their response “There Is No Meaningful Way to Differentiate Between ‘Commercial’ and Other, ‘Noncommercial’ Uses of 3D Printing” and noting that ‘[t]oday, an individual 3D printer may be used for a ‘personal’ or noncommercial use one day, and for a commercial purpose the next.”⁸

FDA Letter

At the request of the Copyright Office, the FDA also submitted a letter addressing a number of the proposed exemptions.⁹ The letter opened with the generally applicable statement

“We note that while allowing circumvention of TPMs will not affect FDA’s jurisdiction over products that continue to meet the device definition under 201(h) of the Federal Food, Drug, and Cosmetic Act (the FDCA) (21 USC 321(h)), and the entities that manufacture them, granting such an exemption for such devices could potentially create regulatory confusion for FDA, medical device manufacturers, and third party software developers that choose to modify medical devices.”

The FDA’s only specific mention of the 3D printing-related exemption request was the following statement:

“Regarding 3D Printing, manufacturers who utilize 3D printing to ultimately manufacture medical devices need to ensure that their products are safe and effective for their intended use. For example, if a 3D printed medical device is intended for insertion into the body, then the manufacturer under FDA regulations would have to demonstrate that the products are safe and effective for that intended use.”¹⁰

The letter then concluded with two recommendations, neither of which raised a concern regarding the 3D printing-related exemption:

“A. FDA recommends that the final rule explain that nothing in the rule will affect the regulation of products that fall within the jurisdiction of other federal agencies. As stated above, third parties that modify medical devices may become regulated manufacturers under the FDCA. As such, it may be useful for those who might

⁸ See Letter from Stratasys, Ltd. to Jacqueline C. Charlesworth, General Counsel and Associate Register of Copyrights, *re: Docket No. 2017-7 Exemptions to Prohibition Against Circumvention of Technological Measures Protecting Copyrighted Works*, (June 29, 2015) available at https://copyright.gov/1201/2015/post-hearing/answers/Class_26_Hearing_Response_Stratasys_Docket_No_2014-07_2015.pdf

⁹ See Letter from Bakul Patel, Associate Director for Digital Health, Center for Devices and Radiological Health, Food and Drug Administratoin, United States Department of Health and Human Services to Jacqueline C. Charlesworth, General Counsel and Associate Register of Copyrights, *re: Section 1201Rulemaking - Proposed Exemption for Medical Devices*, (Aug. 18, 2015) available at https://www.copyright.gov/1201/2015/USCO-letters/FDA_Letter_to_USCO_re_1201.pdf [“FDA Letter”].

¹⁰ *Id.* at 4

circumvent TPMs to understand that other federal laws may apply and that the circumvention exemption is not an exemption from other applicable regulations.

B. We recommend that any final rule make a distinction between bench top testing of devices (where the unit tested is not in clinical use and will not be in clinical use in the future) and testing of devices during clinical use unless, for the latter, institutional review board (IRB) oversight is provided and investigational device exemptions (IDE) regulations are followed, as appropriate.”¹¹

Copyright Office Recommendation

Building on this record, the Copyright Office released its recommendations regarding the exemptions. This recommendation included the qualifying language addressed in this Comment.

The Copyright Office noted that “[t]he record indicates that 3D printing processes are used to produce medical implants, aerospace parts, and consumer goods, which are subject to strict safety standards. It is reasonable to suspect that if these types of items were manufactured using alternative materials or with altered printer software, the resulting goods might not comply with applicable standards.”¹² It did not indicate how these standards are related to copyright law generally or Section 1201 specifically, or why copyright law was the proper mechanism to ensure compliance with the applicable standards.

The Copyright Office also explained that the FDA “reinforced this concern in a letter to the Office, explaining that an exemption for this class might create unintended health and safety risks in relation to medical devices produced using 3D printers.”¹³

Relying on this evidence, the Copyright Office explained “[t]hese safety and regulatory concerns are not copyright-related, but are sufficiently weighty to merit consideration in drafting an exemption.”¹⁴ Recognizing that all parties rejected attempts to draw a distinction between commercial and noncommercial uses, the Copyright Office introduced the qualifying language at the heart of this exemption requests because “the Register finds that it is appropriate to limit the exemption to exclude uses that may be subject to regulation or certification.”¹⁵

The Qualifying Language Excludes Many Legitimate Activities

Whatever the original intent, the qualifying language effectively bans a number of legitimate activities. There are many users that could benefit from using third party feedstock in their 3D printer who are completely unrelated to the medical health or aviation fields. Even users in those fields could benefit from intentionally replacing printer-supplied feedstocks with third party alternatives. There is no evidence that alternative feedstocks are inherently incompatible with the regulatory regimes that might govern the objects created with them.

¹¹ *Id.* at 5

¹² See Maria A. Pallante, Register of Copyrights and Director, U.S. Copyright Office, *Section 1201 Rulemaking: Sixth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention: Recommendation of the Register of Copyrights*, (October 2015) available at <https://www.copyright.gov/1201/2015/registers-recommendation.pdf> at 374.

¹³ *Id.* at 375

¹⁴ *Id.*

¹⁵ *Id.*

However, the qualifying language bans all of those uses. If the 3D printer is used to produce any good or material in commerce and that good or material is subject to any legal or regulatory oversight, the 3D printer operator is excluded from this exemption. The category of goods “subject to legal or regulatory oversight or a related certification process” is almost unimaginably broad. The Consumer Product Safety Commission oversees all consumer products.¹⁶ The United States Customs and Border Protection has the authority to oversee all merchandise arriving on the United States.¹⁷ The legal and regulatory system of the United States is vast and touches on almost any good that could be created by a 3D printer.

There is No Evidence That The Qualifying Language Avoids Harms

The prohibition of legitimate activities might be justified if they were the result of necessary steps to prevent real harms. However, there is no evidence that the qualifying language has any connection to the harms raised to justify its inclusion.

As noted above, concerns around health and safety were first raised by opponent Stratasys during the previous review. Stratasys failed to explain why the requested exemption would negatively impact health and safety, or why the regulatory regimes designed to protect health and safety were inadequate without a prohibition on users having access to third party feedstock.

Although the Recommendation suggests that the FDA raised concerns about the exemption’s impact on medical safety, a review of the FDA’s letter fails to reveal such a concern. The FDA letter began with a general statement that no exemption would impact the FDA’s jurisdiction, immediately followed by a concern that some of the proposed exemptions could create confusion for parties that would modify medical devices.¹⁸ The FDA’s only statement specifically addressing 3D printing was an admonition that “manufacturers who utilize 3D printing to ultimately manufacture medical devices need to ensure that their products are safe and effective for their intended use.”¹⁹ To the extent that this statement suggests any opinion regarding the relationship between the exemption and medical safety, it is that existing FDA regulations are fully adequate to address medical safety concerns. Suggesting that the statement reinforces safety concerns related to the exemption is a miscategorization.

Even If the Qualifying Language Was Narrowly Tailored to Address a Real Safety Concern, Such Concerns Are Beyond the Scope of This Proceeding

The purpose of Section 1201 is to address TPMs that control access to works protected under copyright law.²⁰ There is no reason to believe that Congress crafted the Section in order to grant the Copyright Office broad authority over issues of health or safety concerns as long as those concerns had some imaginable nexus with TPMs. The factors of Section 1201(a)(1)(C)(i)-(v) should be read within the confines of copyright law and policy, not as a mandate to right the wrongs of the world. If the FDA, or any other regulatory agency of the United States Government, believes that it has been insufficiently empowered by Congress to carry out its mission, it should not rely on the Copyright Office to fill the gaps. Instead, that agency should raise its concerns with Congress directly.

16 See, e.g. 15 U.S.C. § 2054(a).

17 See, e.g. 19 C.F.R. 162.6.

18 See FDA letter at 1.

19 See *id.* at 4.

20 17 USC § 1201(a)(1)(A).

In light of this, any attempt to address issues beyond the scope of copyright - and certainly an attempt to wade into areas regulated by entire independent agencies - via this process is improper. Nothing in this proceeding prevents those independent agencies from continuing to regulate activities within their purview.

Neither the Copyright Office nor the participants in this proceeding have the expertise required to address issues as diverse and airline safety and the regulation of implanted medical devices. Participants cannot reasonably be expected to present information regarding non-copyright-related issues, nor should they be expected to refute such information provided by others. Even if participants were able to produce and refute such information, the Copyright Office is poorly positioned to evaluate competing arguments in fields well beyond its area of expertise. Therefore, this proceeding should focus on questions of copyright law and policy, leaving unrelated concerns to the relevant expert agencies.

DOCUMENTARY EVIDENCE

N/A